UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,408	05/09/2001	Carlos Schuler	015225-005910US	5388

21968 7590 07/26/2006	EXAMINER
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070	PATEL, NIHIR B

	ART UNIT	PAPER NUMBER
	3743	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/852,408	SCHULER ET AL.
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
> WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
>   after SIX (6) MONTHS from the mailing date of this communication.
> - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
> - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
>   Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
>   earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>05.11.2006</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-36</u> is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-36</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Response to Arguments

1.   Applicant's arguments filed on May 11th, 2006 have been fully considered but they are

not persuasive. The applicant argues that Bruna does not disclose an aerosol generator for

aerosolizing the drug formulation in response to manual actuation. The examiner disagrees.

Bruna does disclose an aerosol generator for aerosolizing the drug formulation in response to

manual actuation **(see column 6 lines 1-10 and column 8 lines 65-67; the suction applied by**

the patient to the inhale duct in a broad sense is considered to be manual actuation).

The applicant also argues that Bruna does not disclose a control system that controls the

opening of a valve such that the valve is only opened when a force is manually applied to depress

the canister into the housing and when a dosing condition has been satisfied at which time a

locking mechanism is in an active state. Bruna is not relied for a valve that is only open when a

force is manually applied to depress the canister into the housing. Jones discloses a valve that is

only open when a force is manually applied to depress the canister into the housing. Therefore it

would have been obvious to modify Bruna's invention by providing a valve that is only open

when a force is manually applied to depress the canister into the housing as taught by Jones in

order to deliver the required amount if medicament.

Therefore claims 1 through 9, 11 through 18 and 24 through 27 are rejected under 35

U.S.C. 102(b) as being anticipated by Bruna et al. (US 5,692,492), claims 34, 35 and 36 are

rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna et al. (US 5,692,492) in view

of Von Wielligh (US 6,024,097), claims 19 through 22 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Bruna et al. (US 5,692,492) in view of Rubsamen et al. (US 5,694,919)

and claims 28 through 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruna

et al. (US 5,692,492) in view of Jones, Jr. et al. (US 5,724,986) as stated in the preivous office

action dating November 15th, 2005.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing
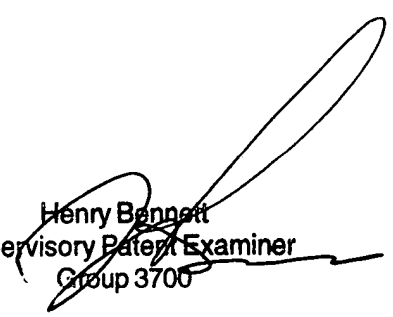
date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The

examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nihir Patel
Art Unit 3743

Henry Bennett
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Group 3700